

REMARKS

Applicant appreciates the thorough examination of the present application as evidenced by the final Office Action dated April 26, 2004 (hereinafter, "Final Action") and the subsequent Advisory Action dated July 28, 2004 (hereinafter, "Advisory Action"). Claims 1–4, 6–14 and 16–19 are pending in this application. Claims 1–4, 6, 11–14 and 16 were amended in the Amendment After Final submitted on October 25, 2004; however, according to the Advisory Action, these amendments were not entered. Applicant has amended Claims 1–4 and 11–14 herein. Support for these amendments can be found throughout the specification as noted below. Accordingly, no new matter is added by the entry of these amendments, and Applicant respectfully requests entry thereof.

The rejections presented in the Final Action, and maintained in the Advisory Action are addressed below.

I. Claim Rejections Under 35 U.S.C. § 112, First Paragraph, Enablement

Claims 1–2, 4, 6–11, 14 and 16–19 stand rejected under 35 U.S.C. § 112, first paragraph, as purportedly not enabled. More specifically, the Office Action states that the specification "does not reasonably provide enablement for practicing the claimed method comprising the administration of antisense oligonucleotides." Office Action, page 2, item 2. Applicant respectfully disagrees with this assertion; however, in an effort to expedite prosecution, Applicant has amended Claim 1 as follows:

1. A method of facilitating vascular growth in cardiac muscle of a human subject in need of such treatment, comprising:
inhibiting activity of EMAP II of SEQ ID NO:4 in said human subject by an amount effective to stimulate vascular growth in said cardiac muscle, wherein said inhibiting step is not carried out by administering a human EMAP II antisense oligonucleotide.

Claim 11 has been similarly amended. Support for these amendments arises from Applicant's ability to claim less than the full scope of disclosure. *See In re Johnson and Farnham*, 194 U.S.P.Q. 187 (C.C.P.A. 1977) (copy previously provided with the Amendment After Final submitted October 25, 2004). Accordingly, Claims

1 and 11 are not directed to an inhibiting step that is carried out by administering a human EMAP II antisense oligonucleotide.

In the Advisory Action, the Examiner states, "Applicant's amendment raises new issues under 35 U.S.C. § 112, for new matter, since there is no support in the specification as filed for the administration of any other compound besides antisense oligonucleotides, wherein the compound is administered in an effective amount to down regulate EMAP II expression." Advisory Action, page 2. Applicant respectfully disagrees with this assertion.

The "test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation." (M.P.E.P. § 2164.01, citing *In re Wands*, 858 F.2d 731, 737). Applicant respectfully submits that one reasonably skilled in the art would be able to make and use the invention as set forth in the amended claims without undue experimentation based upon the disclosure provide in the present specification, and further in view of the information known in the art regarding compounds that inhibit nucleic acid expression. In view of the claim amendments, the specification and the information known in the art, Applicant respectfully submits that one skilled in the art relevant to the present invention would be able to practice the presently-claimed invention without "undue" experimentation.

Accordingly, Applicant respectfully requests that the rejection of Claims 1–2, 4, 6–11, 14 and 16–19 under 35 U.S.C. § 112, first paragraph, as lacking enablement, be withdrawn.

II. Claim Rejections Under 35 U.S.C. § 112, First Paragraph, Written Description

Claims 1–4, 6–14 and 16–19 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. More specifically, the Office Action alleges that "[t]he claims are not limited to use of agents that specifically binds to or inhibits the expression of human EMAP II." Final Action, page 3, item 6. The Final Action further alleges that "the instant claims are not limited to human EMAP II" Office Action, page 4, item 6 cont.

In an effort to expedite prosecution, Applicant has amended Claims 1–4, 6, 11–14 and 16 to include a recitation directed EMAP II of “SEQ ID NO:4.” Applicant has further amended the specification, as noted above, to include sequence identifiers and a substitute sequence listing. Support for these amendments can be found in U.S. Patent No. 5,641,867 to Stern et al. (Stern et al.). Applicant incorporated the disclosure of Stern et al. by reference in its entirety as indicated in the present application on page 6, lines 23-26. Thus, Applicant respectfully submits that no new matter is added by these amendments to the specification and claims, and that these amendments address the Examiner’s concerns regarding written description.

Accordingly, Applicant respectfully requests that the rejection of Claims 1–4, 6–14 and 16–19 under 35 U.S.C. § 112, first paragraph, for failing to comply with the written description requirement, be withdrawn.

III. Double Patenting Rejections

As previously noted in the Amendment After Final submitted on October 25, 2004, Applicant acknowledges the Examiner’s statements in the Final Action regarding the provisional rejection of Claims 1–19 over Claims 1–4 of copending U.S. Patent Application Serial No. 09/928,796 (the ’796 application)¹, and the holding of a response in abeyance until the indication of allowable subject matter as noted in the Final Action.

Conclusion

In view of the foregoing amendments and remarks, Applicant respectfully requests that all outstanding rejections to the claims be withdrawn and that a Notice of Allowance be issued in due course. The Examiner is invited and encouraged to contact the undersigned directly if such contact will expedite the prosecution of the pending claims to issue. In any event, any questions that the Examiner may have should be directed to the undersigned, who may be reached at (919) 854-1400.

No fees are believed due. In the event that additional fees are necessary to allow consideration of this paper, such an extension is also hereby petitioned for

¹ Attorney Docket No. 9022-8CT.

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under 37 C.F.R. § 1.136(a). Any additional fees believed to be due in connection with this paper may be charged to our Deposit Account No. 50-0220.



Respectfully submitted,

A handwritten signature in black ink, appearing to read "Shawna Cannon Lemon".

Shawna Cannon Lemon
Registration No. 53,888

USPTO Customer No. 20792
Myers Bigel Sibley & Sajovec, P.A.
P. O. Box 37428
Raleigh, North Carolina 27627
Telephone: (919) 854-1400
Facsimile: (919) 854-1401

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A handwritten signature in black ink, appearing to read "Susan E. Freedman".

Susan E. Freedman
Date of Signature: November 15, 2004